

**IN THE UNITED STATES DISTRICT COURT FOR
THE MIDDLE DISTRICT OF NORTH CAROLINA**

GENETIC TECHNOLOGIES LIMITED,

Plaintiff,

v.

GLAXOSMITHKLINE LLC,

Defendant.

Civil Action 1:12-cv-00299-CCE-JLW

DEFENDANT

**GLAXOSMITHKLINE LLC'S
REPLY BRIEF IN SUPPORT OF
MOTION TO DISMISS UNDER
FEDERAL RULE OF CIVIL
PROCEDURE 12(b)(6)**

Oral Argument Requested

TABLE OF CONTENTS

	<u>Page</u>
INTRODUCTION	1
I. GTG's Reliance On <i>Ultramercial</i> Is Misplaced.	2
II. The Supreme Court's Decision In <i>Alice</i> Confirms That GTG's Patents Claim Ineligible Subject Matter.....	2
III. None of GTG's Arguments Save Its Claims.....	5
A. GTG's Attempts To Conflate Subject Matter Eligibility With Anticipation Or Obviousness Should Be Rejected.	5
B. The Machine-or-Transformation Test Does Not Rescue GTG's Claims.	8
C. GTG's Preemption Argument Also Fails.	8
D. Claim Construction Is Not Necessary To Decide This Motion.	9
IV. The Court Has Jurisdiction To Grant GSK's Motion.	9
CONCLUSION.....	10

TABLE OF AUTHORITIES

	Page(s)
FEDERAL CASES	
<i>Adams v. Aiken</i> , 41 F.3d 175 (4th Cir. 1994).....	2
<i>Alice Corp. v. CLS Bank Int'l</i> , 134 S. Ct. 2347 (2014).....	passim
<i>Ass'n for Molecular Pathology v. Myriad Genetics, Inc.</i> , 133 S. Ct. 2107 (2013).....	5
<i>Ass'n for Molecular Pathology v. USPTO</i> , 689 F.3d 1303 (Fed. Cir. 2012)	5
<i>Bilski v. Kappos</i> , 130 S. Ct. 3218 (2010).....	8
<i>BuySAFE, Inc. v. Google Inc.</i> , No. 11-1282-LPS, 2013 WL 3972261 (D. Del. July 29, 2013).....	9
<i>Clatterbuck v. City of Charlottesville</i> , 708 F.3d 549 (4th Cir. 2013)	4
<i>Content Extraction & Transmission LLC v. Wells Fargo Bank</i> , Nos. 12-2501, -6960, 2013 WL 3964909 (D.N.J. July 31, 2013)	9
<i>Diamond v. Diehr</i> , 450 U.S. 175 (1981).....	4
<i>Fox Group, Inc. v. Cree, Inc.</i> , 700 F.3d 1300 (Fed. Cir. 2012).....	10
<i>Genetic Techs. Ltd. v. Agilent Techs., Inc.</i> , No. 12-cv-1616, 2014 U.S. Dist. LEXIS 31474 (N.D. Cal. Mar. 7, 2014)	7
<i>In re BRCA1- and BRCA2-Based Hereditary Cancer Test Patent Litig.</i> , MDL No. 2:14-MD-2510, 2014 WL 931057 (D. Utah Mar. 10, 2014)	8
<i>Johnson v. Bd. of Educ.</i> , 457 U.S. 52 (1982)	2

<i>Lockheed Martin Corp. v. Space Systems/Loral, Inc.</i> , 324 F.3d 1308 (Fed. Cir. 2008)	2
<i>Lumen View Tech. LLC v. Findthebest.com, Inc.</i> , No. 13-cv-3599, 2013 WL 6164341 (S.D.N.Y. Nov. 22, 2013)	9
<i>Mayo Collaborative Serv. v. Prometheus Labs., Inc.</i> , 132 S. Ct. 1289 (2012).....	passim
<i>SmartGene, Inc. v. Advanced Biological Labs., S.A.</i> , 852 F. Supp. 2d 42 (D.D.C. 2012), <i>aff'd</i> , 555 Fed. App'x 950 (Fed. Cir. 2014)	7
<i>Spencer v. Earley</i> , 278 F. App'x 254 (4th Cir. 2008).....	2
<i>Ultramercial, Inc. v. Hulu, LLC</i> , 722 F.3d 1335 (Fed. Cir. 2013), <i>vacated</i> , <i>WildTangent, Inc. v. Ultramercial, LLC</i> , No. 13-255, 2014 U.S. LEXIS 4647 (U.S. June 30, 2014)	2, 7, 8
FEDERAL STATUTES	
35 U.S.C. § 101.....	passim
35 U.S.C. § 102.....	1, 5
35 U.S.C. § 103.....	1, 5, 7
35 U.S.C. § 302.....	7
OTHER AUTHORITIES	
<i>Neilson v. Hartford</i> , Webster's Patent Cases (1841)	4

INTRODUCTION

Despite the efforts of plaintiff Genetic Technologies Ltd. (“GTG”) to muddy the waters, this case is simple. GTG’s patents are based on the alleged discovery of a naturally existing correlation between variations in coding and noncoding DNA. GTG’s claims merely append conventional steps to that natural law. This combination of conventional steps and a natural law is not eligible for patenting under 35 U.S.C. § 101.

GTG’s arguments to the contrary fail. As an initial matter, GTG largely ignores the Supreme Court’s order vacating a case that figures prominently in GTG’s opposition, as well as the fatal effect on its arguments of the Supreme Court’s recent decision in *Alice Corp. v. CLS Bank International*, 134 S. Ct. 2347 (2014). In addition, GTG’s misguided effort to conflate the eligibility requirement of § 101 with the novelty and nonobviousness requirements of 35 U.S.C. §§ 102 and 103 cannot save GTG’s claims. GTG repeatedly states or suggests that the question to be answered by the Court is whether the steps of the claims are routine or conventional *as applied to the natural law*. That, however, is not the correct framework for analyzing patentability. Rather, the question to be answered by the Court is whether the portions of the claim, *apart from the natural law*, add anything inventive to the claims. As set forth below and in the opening brief, they do not.

Thus, GTG’s allegations are deficient as a matter of law, and the Court should grant defendant GSK’s motion to dismiss GTG’s Second Amended Complaint (“SAC”).

I. GTG’s Reliance On *Ultramercial* Is Misplaced.

GTG repeatedly relies on the Federal Circuit’s decision in *Ultramercial, Inc. v. Hulu, LLC*, 722 F.3d 1335 (Fed. Cir. 2013) (GTG Br. 9, 10, 12, 16, 17, 18, 19, 20, 21, 23), but that decision has been *vacated* by the Supreme Court and remanded to the Federal Circuit “for further consideration in light of” the Supreme Court’s decision in *Alice*. See *WildTangent, Inc. v. Ultramercial, LLC*, No. 13-255, 2014 U.S. LEXIS 4647 (U.S. June 30, 2014) (per curiam). Unless explicitly limited, which is not the case with respect to the order at issue, a “GVR” order granting certiorari, vacating, and remanding vacates the prior decision in its entirety. See *Johnson v. Bd. of Educ.*, 457 U.S. 52, 53-54 (1982) (per curiam); *Lockheed Martin Corp. v. Space Systems/Loral, Inc.*, 324 F.3d 1308, 1310 (Fed. Cir. 2008); *Spencer v. Earley*, 278 F. App’x 254, 261-62 (4th Cir. 2008) (nonprecedential); *Adams v. Aiken*, 41 F.3d 175, 179 (4th Cir. 1994). GTG’s reliance on *Ultramercial* is thus misplaced.

II. The Supreme Court’s Decision In *Alice* Confirms That GTG’s Patents Claim Ineligible Subject Matter.

GTG fails substantively to address the Supreme Court’s recent decision in *Alice Corp. v. CLS Bank International*, 134 S. Ct. 2347 (2014), which reaffirmed the two-step analysis articulated in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 132 S. Ct. 1289 (2012). Under that framework, courts must first “determine whether the claims at issue are directed to … patent-ineligible concepts,” such as “laws of nature” or “natural phenomena.” *Alice*, 134 S. Ct. at 2355. “If so,” courts “then ask, what else is there in the claims?” *Id.* (emphasis added; quotation marks, and brackets omitted). At

this second step, a court must “consider the elements of each claim *both individually and as an ordered combination* to determine whether the *additional elements*,” or “*additional features*,” of the claim impart an “inventive concept” beyond the ineligible subject matter. *Alice*, 134 S. Ct. at 2355, 2357 (emphases added; quotation marks omitted).

GTG concedes that the “correlation between non-coding and coding polymorphisms”—the discovery on which its patents are based—is naturally occurring.” GTG Br. 17.¹ Thus, the first prong of the *Alice/Mayo* test is met. Moreover, the additional steps in GTG’s claims fail to transform them into patentable subject matter. ““Simply appending conventional steps, specified at a high level of generality,’ [i]s not ‘enough’ to supply an ‘inventive concept.’” *Alice*, 134 S. Ct. at 2357 (quoting *Mayo*, 132

¹ GTG’s assertion that its claims do not “recite” this law of nature, but rather “recite” only an “application of” the law of nature, GTG Br. 17, misses the mark. Even if that were an accurate description of GTG’s claims, a claim that does no “more than simply state the law of nature while adding the words ‘apply it,’” does not satisfy the *Mayo* test. *Mayo*, 132 S. Ct. at 1294; *see also Alice*, 134 S. Ct. at 2357. In addition, GTG’s assertion that “the use of the correlation as a surrogate is not naturally occurring,” GTG Br. 17, is both puzzling and irrelevant. The use of the metabolite levels in *Mayo* as a surrogate for the proper drug dosage was not naturally occurring, either. There is no requirement that all the steps of a laboratory technique based on a law of nature themselves occur in nature in order for the technique to constitute ineligible subject matter. *See Mayo* at 1294, 1296-98.

S. Ct. at 1297, 1299-1300).² Here, by the applicant's own admission, the inventor did not "invent[] a new way to analyze genetic loci," but rather "found that when *prior art techniques* are applied to the non-coding sequences, the result can be more informative than [direct] analysis of the coding regions." Suppl. Preliminary Am. 6 (Jan. 14, 1993) ('179 Patent) (A66) (emphasis added).³ GTG's patent specifications and prosecution histories repeatedly state that the prior art amplification and analysis techniques were not merely known, but routine and widely utilized. *See, e.g.*, '179 Patent, 16:28-29; '762 Patent, 22:24-25; *id.* 25:25-28; *see also* GSK Br. 14-15, 21 n.11. GTG cannot create a dispute by contradicting statements in its own patents.

GTG's attempt to analogize its claims to the man-made cDNA and screening-method claims that were held patent eligible by the Supreme Court and the Federal Circuit in *Myriad*, respectively (GTG Br. 14-15), also lacks merit. GTG's patents do not

² GTG's assertion that the claims at issue are similar to those held patentable in *Neilson v. Hartford*, Webster's Patent Cases, at 371 (1841), and *Diamond v. Diehr*, 450 U.S. 175 (1981), lacks merit. GTG Br. 23-24. Those cases are readily distinguishable. The claims in *Neilson* covered a receptacle for heated air interposed between a blowing apparatus and the furnace. Webster's Patent Cases, at 371. *Diehr* concerned claims to a method for transforming raw rubber into molded cured rubber, which applied a mathematical algorithm in a novel way that went well beyond a claim on the algorithm itself. *See Diehr*, 450 U.S. at 179, n.5. In this case, however, the conventional techniques appended to GTG's claims fail to add anything inventive to the natural law.

³ The prosecution histories cited by GSK are subject to judicial notice and may be considered under Rule 12(b)(6). *See* GSK Br. 7. In contrast, the declarations attached to GTG's opposition brief are not public records and do not fall within any other category of documents that the Court may consider under Rule 12(b)(6). *See Clatterbuck v. City of Charlottesville*, 708 F.3d 549, 557 (4th Cir. 2013).

claim any DNA sequences at all. As such, GTG’s comparison of its claims to the *Myriad* cDNA claims is inapt. GTG’s efforts to analogize its claims to the method claim held patent eligible in the Federal Circuit’s decision in *Myriad*, fare no better. The only method claim held patentable in that case (claim 20) involved manmade, transformed cells that did not occur in nature.⁴ *Ass’n for Molecular Pathology v. USPTO*, 689 F.3d 1303, 1333-37 (Fed. Cir. 2012).

In sum, GTG’s patent claims do not satisfy the two-prong test set forth in *Mayo* and *Alice*.

III. None of GTG’s Arguments Save Its Claims.

A. GTG’s Attempts To Conflate Subject Matter Eligibility With Anticipation Or Obviousness Should Be Rejected.

Throughout its opposition, GTG inappropriately attempts to conflate subject matter eligibility analysis under § 101 with invalidity analyses based on anticipation (§ 102) and/or obviousness (§ 103). For example, GTG asserts that it was not “routine” or “conventional” to apply amplification techniques to non-coding DNA *for the specific*

⁴ GTG’s assertion that the Supreme Court reviewed Myriad’s method claims because one method claim “was appealed to the Supreme Court but certiorari was denied” (GTG Br. 15, n.12), is incorrect. The denial of certiorari confirms that the Supreme Court did *not* review the patent eligibility of the Myriad method claims.

purpose of obtaining information about variations in coding DNA. GTG Br. 3-7, 20-21.⁵

Even if true, this assertion is irrelevant under § 101, because the Court must first *set aside* the allegedly novel law of nature, and then ask whether the claims “contain *other* elements” that collectively impart an ““inventive concept,”” or whether, conversely, the “*additional* steps consist of well-understood, routine, conventional activity already engaged in by the scientific community.” *Mayo*, 132 S. Ct. at 1294, 1298 (emphases added); *see Alice*, 134 S. Ct. at 2355, 2357; GSK Br. 9. Here, examining correlations between non-coding and coding DNA is nothing more than an application of the underlying law of nature, and using conventional techniques to do so lacks any “inventive concept” apart from the law of nature itself. By failing to distinguish between the “*additional elements*” and the law of nature, *see Alice*, 134 S. Ct. at 2355, GTG

⁵ GTG also suggests that a factual dispute exists over whether non-coding DNA had ever been amplified at all. GTG Br. 3, 10-11 n.9. But GTG’s own admissions make clear that there is no dispute that known amplification techniques could be applied to any form of DNA, including non-coding regions. *See Am. in Resp. to Final Office Action of March 21, 1994*, at 14 (June 20, 1994) (’762 Patent) (A166) (“[O]ne skilled in the art understands that the amplification procedure is the same regardless of the DNA sequence to be amplified.”). Indeed, GTG has not argued, nor could it argue, that there is any feature of non-coding DNA that makes the amplification technique different or inapplicable.

improperly conflates § 101 with the prior art-based grounds of invalidity. *See* GTG Br. 5-7, 11 n.9, 18, 20-21.⁶

For the same reason, the PTO’s reasons for granting the ’179 patent (GTG Br. 5) and its decisions in reexaminations of various claims of that patent (*id.* at 5-7, 20-21), are irrelevant to the § 101 analysis. The PTO’s reasoning for granting the ’179 patent only addressed whether the combination of prior art teachings anticipated the claims as a whole, including the law of nature on which they are based, and did not address section 101 issues at all. *Id.* at 5.

Furthermore, section 101 challenges may not even be raised in reexaminations, which are limited to prior art-based grounds of invalidity. 35 U.S.C. § 302; *SmartGene, Inc. v. Advanced Biological Labs., S.A.*, 852 F. Supp. 2d 42, 50 (D.D.C. 2012), *aff’d*, 555 Fed. App’x 950 (Fed. Cir. 2014) (nonprecedential). Thus, the outcome of those proceedings has no bearing whatsoever on the issues raised in the instant motion. Indeed, as was the case with the original ’179 patent grant, the examiners relied on the law of nature itself as the discovery that distinguished the claims from the prior art under § 103,

⁶ As set forth in more detail in GSK’s opening brief (at 24), GTG’s reliance on the district court’s decision in *Genetic Technologies Ltd. v. Agilent Technologies, Inc.*, No. 12-cv-1616, 2014 U.S. Dist. LEXIS 31474 (N.D. Cal. Mar. 7, 2014), is similarly misplaced. Among other things, the *Agilent* court appeared to misapply Supreme Court precedent by failing to set aside the law of nature when it asked whether “the additional elements” of the methods supply an inventive concept that might make the claim eligible under § 101. Moreover, the *Agilent* court relied in significant part on the now-vacated *Ultramerical* decision. *Id.* at *11-12 & n.6, *16-21 & nn.12-13, *25-26.

see GTG Br. 5-7, confirming that once this law of nature is set aside—as it must be for purposes of § 101—the *additional* elements lack an “inventive concept.”

B. The Machine-or-Transformation Test Does Not Rescue GTG’s Claims.

GTG’s attempt to invoke the so-called machine-or-transformation test by arguing that the primers used to amplify DNA regions are “a machine,” GTG Br. 21-22, is unavailing. First, the Supreme Court held that the machine-or-transformation test does not conclusively determine whether a claim is patent eligible. *Mayo*, 132 S. Ct. at 1302-03; *Bilski v. Kappos*, 130 S. Ct. 3218, 3225-26 (2010). Moreover, GTG’s own patent indicates that the primers “preferably have a nucleotide sequence that is identical to a portion of the DNA sequence to be amplified or its complement.” *See* ’179 Patent, 12:12-14. Because these primers can consist of naturally occurring genomic DNA sequences, they are products of nature, and not machines. *See In re BRCA1- and BRCA2-Based Hereditary Cancer Test Patent Litig.*, MDL No. 14-MD-2510, 2014 WL 931057, at *41-48 (D. Utah Mar. 10, 2014) (DNA identical in sequence to naturally occurring DNA is a non-patentable product of nature). Therefore, the machine-or-transformation test cannot rescue GTG’s claims.

C. GTG’s Preemption Argument Also Fails.

GTG relies on the vacated *Ultramercial* decision for the proposition that the Court is required to conduct a preemption inquiry to determine patent eligibility. GTG Br. 10, 19-20. To the extent that the *Ultramercial* court even intended to define “inventive concept” narrowly as a lack of preemption, the Supreme Court rejected this definition in

Alice. 134 S. Ct. at 2355. *Alice* makes clear that “preemption” is not an independent element that must be found to support a holding of ineligibility. *Id.* Rather, it “simply reinforces [the] conclusion that the processes described in the patent[] are not patent eligible.” *Mayo*, 132 S. Ct. at 1302 (emphasis added).

D. Claim Construction Is Not Necessary To Decide This Motion.

GTG’s effort to manufacture a claim construction issue that affects the analysis here fails. GTG Br. 11. Although GTG alludes to an unspecified disagreement regarding step (e) of claim 1 of the ’762 Patent, *id.*, GTG neither proposes an alternative “construction” nor explains how its unarticulated construction would alter the § 101 analysis. In any event, district courts routinely address § 101 challenges without claim construction. *See, e.g., Lumen View Tech. LLC v. Findthebest.com, Inc.*, No. 13-cv-3599, 2013 WL 6164341, at *15 (S.D.N.Y. Nov. 22, 2013); *Content Extraction & Transmission LLC v. Wells Fargo Bank*, Nos. 12-2501, -6960, 2013 WL 3964909, at *13 (D.N.J. July 31, 2013); *BuySAFE, Inc. v. Google Inc.*, No. 11-1282, 2013 WL 3972261, at *1 n.1 (D. Del. July 29, 2013).

IV. The Court Has Jurisdiction To Grant GSK’s Motion.

GTG asserts that the Court must put off ruling on GSK’s Motion “because a case or controversy does not yet exist for all claims” of any of the patents. GTG Br. 16 n.13. The only relief sought by GSK at this stage is for the Court to dismiss GTG’s amended complaint with prejudice, GSK Mot. To Dismiss (D.I. 77); GSK Br. 1-2, 25, and the

Court clearly has jurisdiction to dismiss a complaint brought by GTG.⁷ Moreover, GTG concedes that the claims addressed by GSK's opening brief are "exemplary," and makes no effort to identify any claims whose eligibility does not depend on these claims. GTG Br. 16 n.13. A complaint is not a license to embark on a fishing expedition to determine whether there is a valid infringement claim in the first place. In the face of GSK's motion challenging the second amended complaint for failure to state a claim, GTG has not identified a single, patentable claim that can be asserted against GSK. Deferring resolution of GSK's § 101 challenge would be inconsistent with Rule 12(b)(6), which vests courts with an important gatekeeping function intended to avoid unnecessary and costly discovery concerning patents and allegations that are plainly deficient, especially where, as here, discovery would asymmetrically burden defendants.

CONCLUSION

For the foregoing reasons, and those stated in GSK's opening brief, the Court should dismiss GTG's Second Amended Complaint, with prejudice.

⁷ GTG's reliance on *Fox Group, Inc. v. Cree, Inc.*, 700 F.3d 1300 (Fed. Cir. 2012), is misplaced. In *Fox Group*, the Federal Circuit held that the district court lacked jurisdiction over a defendant's claim for a declaratory judgment of invalidity where the patent owner had expressly "narrowed the scope of its asserted claims before the court ruled." *Id.* at 1307-08 (internal quotation marks omitted).

Respectfully submitted this 1st day of August, 2014.

/s/ John F. Morrow, Jr.
John F. Morrow, Jr. (N.C. State Bar No. 23382)
David R. Boaz (N.C. State. Bar. No. 44229)
WOMBLE CARLYLE SANDRIDGE & RICE, LLP
One West Fourth Street
Winston-Salem, NC 27101
Telephone: 336-721-3584
Facsimile: 336-733-8429
E-Mail: jmorrow@wCSR.com

Of Counsel:

Amy K. Wigmore
Tracey C. Allen
WILMER CUTLER PICKERING
HALE AND DORR LLP
1875 Pennsylvania Ave. NW
Washington, DC 20006

Attorneys for Defendant GlaxoSmithKline LLC

CERTIFICATE OF SERVICE

I certify that on August 1, 2014, I filed the foregoing document using this Court's ECF system, which will serve a copy via email to all counsel of record.

/s/David R. Boaz
David R. Boaz (NCSB 44229)
WOMBLE CARLYLE SANDRIDGE &
RICE, LLP
One West Fourth Street
Winston-Salem, NC 27101
Phone: 336-721-3538
Fax: 336-733-8429
E-Mail: dboaz@wCSR.com